

REMARKS/ARGUMENTS

Claims 1-17 are pending in the instant application. Claims 1-3 and 6-14 stand rejected under 35 USC 102(b) as being anticipated by Strecker (US 3898044). Claim 4 stands rejected under 35 USC 103(a) as being unpatentable over Strecker in view of Lu ("Characterisation of Closed-cell Cellular Aluminium Alloys" J. Mat. Sci. 2001 36:2773-86). Claim 5 stands rejected under 35 USC 103(a) as being unpatentable over Strecker in view of Homer (US 4582638). Claims 15-17 stand rejected under 35 USC 103(a) as being unpatentable over Strecker. The application has been amended. Claims 1 and 14 have been amended. Claim 7 has been canceled with its limitations incorporated into claim 1. Applicants respectfully submit that none of the amendments constitute new matter in contravention of 35 U.S.C. §132. Reconsideration is respectfully requested.

Claims 1-3 and 6-14 are rejected under 35 USC 102(b) as being anticipated by Strecker et al (US 3898044). This rejection is respectfully traversed.

The present invention provides a device for producing a fluid with a radioactive constituent. The device includes a shielded chamber with an elongate opening for receiving an isotope container, here an ion exchange column. The chamber supports a first needle at its bottom so that as the column is inserted into the chamber the first needle penetrates thereinto. The chamber includes a closure that is inserted into the opening so as to both shield the contents of the column as well as to provide a supported second needle which penetrates the

opposite end of the column. Thus the column is penetrated by each needle during the act of assembling the device. However, in order to ensure that each needle penetrates a sufficient distance into the column, the first and second needles each support a compressible buffer which includes a spacer element. The spacer element ensures that column is properly positioned within the opening so that each needle is inserted the appropriate distance into the column.

Strecker, on the other hand, provides a shielded container which does not provide for penetration into its inserted fluid housing (a nuclide generator) until after the container has been assembled around the housing/generator. The Strecker container provides a container cap at each end of an opening in the container, each cap accommodates a needle to be inserted therethrough.

In order to anticipate a claimed invention, a reference must disclose each and every element of the claimed invention. Strecker fails to disclose an ion exchange column and further fails to disclose a compressible buffer having a spacer for ensuring the proper depth of penetration of the needles. Both of these failings are shortcomings of Strecker.

The Office cites the darker cross-hatched component in Figure 7 of Strecker as a spacer. However, this unidentified component (which is typically just a foil wrap for holding a septum to a container rim) is not even shown to be in contact with any of the interior spaces of the Strecker device. Since this component does not come into contact between two other components, Applicant respectfully submits that it cannot possibly function as a spacer.

Additionally, this unidentified component includes a large opening through which the needle passes. This large opening also prevents the component from acting as a spacer for the needle since it therefore does not come into contact between the needle and anything else. Applicants respectfully submit that any motivation to replace this component with a compressible buffer having a spacer in accordance with the present invention would require improper hindsight by the Office.

Therefore, as Strecker fails to disclose each and every element of the present invention, Applicants respectfully submit that the instant invention is patentably distinct thereover. Similarly, by virtue of their being dependent on claim 1, Applicant furthermore submits that claims 2-13 are also not anticipated by Strecker.

Claim 14 has been amended to include the limitation disclosed on page 6 lines 16-19 of the present specification, i.e. that the isotope container is preferably an ion exchange column and each of its opposing ends preferably includes a frangible seal adapted to be pierced by and to seal around the respective first and second hollow needles.

As outlined above in relation to claim 1, Applicant submits that Strecker does not teach the presence of compressible buffers incorporating spacers for properly positioning the needles within a ion exchange column. Strecker therefore does not teach the step of having the spacers ensure the determining the position of the isotope container within the chamber. Claim 14 includes the step of closing the shielded chamber by positioning the chamber closure in the opening and bringing the first hollow needle and the first compressible buffer

into contact with the isotope container whereby the spacer determines the positioning of the isotope container within the shielded container.

Again referring to Figure 7 of Strecker, there is no spacer element provided to be positioned between the isotope container the inner surfaces of the shielding. Strecker thus fails to anticipate claim 14 or its dependent claims 15-17.

Accordingly, as Strecker fails to disclose each and every element of claims 1-6 and 13-17, Applicant therefore submits that claim 14 and its dependent claims 15-17 are patentably distinct thereover. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 4 is rejected under 35 USC 103(a) as being unpatentable over Strecker in view of Lu et al (Journal of Materials Science 2001; 36: 2773-86). This rejection is respectfully traversed.

Lu discloses a semi-open cell aluminum alloy foam, illustrated in Figure 9 to have open and closed pores therein of around 1mm in diameter. Applicant respectfully submits that a stopper made of such a semi-open cell foam would not provide the necessary degree of sterility and radiological protection required by the present invention. As a consequence, Applicant submits that the skilled person would not look to the teachings of Lu to modify those of Strecker in order to arrive at the present invention.

Furthermore, as claim 4 depends from allowable claim 1, Applicants respectfully submit that claim 4 is likewise allowable over the cited art. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over Strecker in view of Homer et al (US 4582638). This rejection is respectfully traversed.

Homer teaches a method and means for disposal of radioactive waste, comprising use of a storage container. The storage container includes gaskets which serve to provide a fluidtight joint and also to allow limited freedom of movement for a component of the storage container. Applicant submits that a gasket would not be suitable for association with one or each of the pierceable stoppers of Strecker to determine the position of the isotope container within the shielded chamber. Therefore the teachings of Homer do not serve to bring the teachings of Strecker any closer to the device of the present invention.

Furthermore, the teachings of Homer relate to a method and means for solidifying nuclear waste in resin for permanent disposal. In common with the present invention, radiological safety is important in disposal of nuclear waste. However, there are fundamentally different considerations in advancing methods and means for disposal of nuclear waste compared with methods and means for generating radionuclides suitable for use in radiopharmaceuticals. Applicant submits that the skilled person would not look to the field of nuclear waste disposal for improvements applicable to a radionuclide generator.

Moreover, as claim 5 depends from allowable claim 1, Applicants respectfully submit that claim 5 is likewise allowable over the cited art. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 15-17 are rejected under 35 USC 103(a) as being unpatentable over Strecker. This rejection is respectfully traversed.

As submitted above, Applicant believes that independent claim 14 is patenably distinct over Strecker. Furthermore, Strecker does not teach the method of the present invention. Mounting the compressible buffer and spacer around the first needle of the present invention before the needle is introduced into the isotope container allows for accurate positioning of the buffer and spacer around the needle before the needle contacts any radioactivity. Therefore an advantage is provided in present claim 14 over the teachings of Strecker. Strecker does not teach or suggest this order of constructing the device.

Moreover, as claims 15-17 depend from allowable claim 14, Applicants respectfully submit that claims 15-17 are likewise allowable over the cited art. Reconsideration and withdrawal of the rejection are respectfully requested.

Appl. No. 10/511,405
Amdt. Dated July 17, 2008
Reply to Office action of March 17, 2008

Based on the above amendments and remarks, Applicants respectfully submit that the instant application, including claims 1-6 and 8-17, is in condition for allowance. Favorable action thereon is respectfully requested.

Any questions with respect to the foregoing may be directed to Applicants' undersigned counsel at the telephone number below.

Respectfully submitted,

/Robert F. Chisholm/
Robert F. Chisholm
Reg. No. 39,939

GE Healthcare, Inc.
101 Carnegie Center
Princeton, NJ 08540
Phone (609) 514-6905

I:\IP\Response to Office Action\PZ\PZ0219 (07-17-08).doc